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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,249	11/10/2005	Patrick Forenzo	4-32907A	2466

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EXAMINER	
KUDLA, JOSEPH S	
ART UNIT	PAPER NUMBER
1611	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/549,249	FORENZO ET AL.	
	Examiner	Art Unit	
	Joseph S. Kudla	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *14-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/12/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Election/Restriction

1. Applicants' election with traverse in the reply filed on January 21, 2008 is acknowledged. The traversal appears to be on the ground(s) that the common technical feature has been mischaracterized and that the common technical feature is a liquid oral dosage of 5-methyl-2-(2'-chloro-6'fluoroanilino)phenylacetic acid. Applicants' argument is not found persuasive because the common technical feature Applicant identifies is anticipated by Gimona et al. (U.S. Patent Publication US 2002/0061932 and cited by Applicant). Gimona et al. teach the "immediate release pharmaceutical compositions (a pharmaceutical composition comprising 5-methyl-2-(2'-chloro-6'fluoroanilino)phenylacetic acid (Abstract)) for use in the kits and methods of the invention containing the active ingredient may be in a form suitable for oral use, for example, as… aqueous or oily suspensions…" (page 2, paragraph 28, sentence 1).

The requirement is still deemed proper and is therefore made FINAL.

2. Applicant's January 21, 2008 correspondence elects Group I, which encompasses claims 1-13. Applicant elects the antifoaming agent as simethicone and the preserving agent as a mixture of propylparaben and methylparaben. The inventions contained in groups II-IV, encompassing claims 14-22, are withdrawn from consideration as being drawn to non-elected subject matter. See 37 CFR 1.142(b). Accordingly, the subject matter now under consideration is drawn to claims 1-13.

[**Note**: In reference to the statement disclosed on page 2, paragraph 3, sentence 3 of Applicant's Remarks/Arguments in the January 21, 2008 correspondence, Applicant states, "As such, applicants do not elect the presence of an antifoaming agent or a preservative." Applicant is reminded, only the cancellation of claims will successfully withdraw the claim limitations within the elected invention. As such, the claim limitations containing reference to antifoaming agents or preservatives will be considered on the merits.]

Priority

3. This application claims priority to International Application PCT/EP04/02528, filed March 11, 2004, and the U.S. Provisional Application 60/454,145, filed March 12, 2003. Priority is acknowledged.

Information Disclosure Statement

4. The Information Disclosure Sheet (IDS) correspondence submitted by Applicant on September 12, 2005 is acknowledged. The references have been reviewed to the extent each is a proper citation on a U.S. Patent.

Oath/Declaration

[**Note**: The Declaration correspondence, filed November 10, 2005, contains an incorrect entry for the filing year for the International Application. Specifically, the filing date for the International Application PCT/EP04/02528, filed March 11,

2004, incorrectly states the year 2005. However, the Application Data Sheet correspondence dated September 12, 2005 contains the correct information; therefore, no further action is necessary.]

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1 and 5-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitations "about" and "between about" in claims 1 and 5-7 are indefinite. The Examiner is unable to ascertain from the instant specification the metes and bounds of the recitations. Without further disclosure from Applicant, the phrases are unclear and confusing.

Appropriate action is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gimona et al. (U.S. Patent Publication US 2002/0061932 and cited by Applicant), in view of all Brubaker et al. (U.S. Patent Publication US 2002/0028794) and Luber et al. (U.S. Patent 6,103,260).

Gimona et al. teach a pharmaceutical composition comprising 5-methyl-2-(2'-chloro-6'fluoroanilino)phenylacetic acid (Abstract). Gimona et al. teach the "immediate release pharmaceutical compositions for use in the kits and methods of the invention containing the active ingredient may be in a form suitable for oral use, for example, as... aqueous or oily suspensions..." (page 2, paragraph 28, sentence 1). Gimona et al. teach the "immediate release formulations useful in the practice of the invention intended for oral use and may be prepared according to any method known in the art for the manufacture of immediate release pharmaceutical compositions (page 3, paragraph 37, sentence 1).

Gimona et al teach a pharmaceutical composition that contains 5-methyl-2-(2'-chloro-6'fluoroanilino)phenylacetic acid, microcrystalline cellulose, croscarmellose sodium (*id est*, carboxymethylcellulose sodium) and water (Page 5, Table 2). It would have been obvious to one of ordinary skill in the art at the time of the invention that the pharmaceutical composition taught by Gimona et al., which includes aqueous suspensions and a suspending agent and water, that Gimona et al. would render instant claim 1 obvious. It would have been obvious to one of ordinary skill in the art at the time of the invention that the suspending agents taught by Gimona et al., which includes microcrystalline cellulose and croscarmellose sodium, that Gimona et al. would render instant claim 2 obvious.

Gimona et al. does not teach the remaining disclosed excipients or the pH range for the composition within the instant claim set.

Brubaker et al. teach an oral pharmaceutical composition in the form of a stable suspension in water for magesterol acetate (Abstract). Brubaker et al. teach the benefits of a magesterol acetate suspension are increased solubility and ease of use for patients that have difficulty swallowing (page 1, paragraph 3, last sentence and paragraph 4, first sentence). Brubaker et al. teach the suspension contains wetting agents, suspending agents, preservatives and buffers (page 3, paragraph 39). Specific wetting agents known in the art to be useful for suspensions include poloxamer and polyoxyl 40 castor oil (page 2, paragraph 36). Specific suspending agents known in the art to be useful for suspensions include xanthan gum, carregeenan, sodium carboxymethylcellulose

and a mixture of microcrystalline cellulose and carboxymethylcellulose sodium (page 3, paragraph 40). Specific preservative agents known in the art to be useful for suspensions include sodium benzoate, benzoic acid, butylparaben, ethylparaben and methylparaben (page 3, paragraph 42). Specific buffer systems known in the art to be useful in adjusting the pH of the suspension include citric acid/sodium citrate and succinic acid/sodium succinate (page 3, paragraph 43). Brubaker et al. teach a specific embodiment of a suspension formulation that includes the active ingredient, a wetting agent (polyoxyl 35 castor oil), two suspending agent used in conjunction (microcrystalline cellulose and carboxymethylcellulose sodium), a buffer system (citric acid/sodium citrate), a preservative (sodium benzoate) and water (page 4, paragraph 52). It would have been obvious to one of ordinary skill in the art at the time of the invention that the pharmaceutical composition taught by Brubaker et al., which includes wetting agent, *id est,* poloxamer and polyoxyl 40 castor oil, that Brubaker et al. would render instant claims 3 and 4 obvious and that the generic term poloxamer would also encompass all poloxamers, such as poloxamer 188, which renders instant claim 7 obvious. It would have been obvious to one of ordinary skill in the art at the time of the invention that the suspending agents taught by Brubaker et al., which includes microcrystalline cellulose and croscarmellose sodium in conjunction, that Brubaker et al. would render instant claim 8 obvious. It would have been obvious to one of ordinary skill in the art at the time of the invention that the buffer systems taught by Brubaker et al., which includes citric acid/sodium citrate and succinic acid/sodium succinate, that Brubaker et al.

would render instant claims 9 and 10 obvious and allow for the modulation of the pH as specified within the instant invention, thus rendering instant claims 1 and 5-7 obvious. It would have been obvious to one of ordinary skill in the art at the time of the invention that the preservative agents taught by Brubaker et al., which includes sodium benzoate, benzoic acid, butylparaben, ethylparaben and methylparaben, that Brubaker et al. would render instant claims 12 and 13 and that the single use of a preservative or a combination of propyl paraben and methyl paraben, as was elected in the correspondence by applicant filed January 21, 2008, would render instant claim 13 obvious.

Luber et al. teach "the clinical use of simethicone is based on its antifoaming properties. Silicone antifoams spread on the surface of aqueous liquids, forming a film of low surface tension and thus causing the collapse of foam bubbles (column 1, lines 24-28). Luber et al. each that "simethicone can be administered orally as a liquid preparation or as a solid form" (column 1, lines 36-37). It would have been obvious to one of ordinary skill in the art at the time of the invention that during the processing of the formulation, if one incurred problematic foaming, the use of an antifoaming agent, such as simethicone, would be employed and that simethicone, a silicone antifoam useful in liquid preparations could be utilized. Therefore, the silicone antifoam, simethicone taught by Luber et al. would render instant claim 11 obvious.

It would have been obvious to one of ordinary skill in the art at the time of the invention that one trying to overcome the limitations of solubility of an active ingredient, as well as, make a formulation for those who have difficulty

swallowing solid-oral dosages would have been aware of solvent systems for a suspension formulation as described by Brubaker et al.

The teachings of Gimona et al. in view of all Brubaker et al. and Luber et al. render the claimed invention obvious.

No claims allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph S. Kudla whose telephone number is (571) 270-3288. The examiner can normally be reached on 9am - 5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Joseph S. Kudla/
Examiner, Art Unit 1611
April 3, 2008

/Michael P Woodward/
Supervisory Patent Examiner, Art Unit 1615